510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K072346

Submitter:

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NOV 2 9 2007

- **Contact Person:**

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- **Date Prepared:**

August 8, 2007

Name of the devices:

- **Trade/Proprietary Name:** PM-7000 Patient Monitor
- **Common Name:** Patient Monitor
- **Classification**

21 CFR 870.1025	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Class II
21 CFR 870.1025	Detector and Alarm, Arrhythmia	Class II
21 CFR 870.1025	Monitor, ST Segment with Alarm	Class II
21 CFR 870.2300	Cardiac monitor (including cardiotachometer and rate alarm)	Class II
21 CFR 870.1130	Non-Invasive blood pressure measurement System	Class II
21 CFR 870.1110	Blood pressure computer	Class II
21 CFR 870.2900	Cable, transducer and electrode, patient, (including connector)	Class II
21 CFR 880.2910	Clinical Electronic Thermometers –	

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	Temperature Monitor with Probe	Class II
21 CFR 870.2700	Oximeter, Pulse	Class II
21 CFR 870.2710	Ear Oximeter, Pulse	Class II
21 CFR 868.1400	Carbon Dioxide Gas Analyzer	Class II
21 CFR 868.1500	Enflurane gas analyzer	Class II
21 CFR 868.1500	analyzer, gas, desflurane, gaseous-phase (anesthetic concentration)	Class II
21 CFR 868.1500	analyzer, gas, sevoflurane, gaseous-phase (anesthetic concentration)	Class II
21 CFR 868.1500	analyzer, gas, isoflurane, gaseous-phase (anesthetic concentration)	Class II
21 CFR 868.1620	Halothane gas analyzer	Class II
21 CFR 868.1700	Nitrous Oxide gas analyzer	Class II
21 CFR 868.1720	Oxygen gas analyzer	Class II

Legally Marketed Predicate Devices:

K#070791, PM Series Patient Monitors, Model PM-9000 Express, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.

Description:

The PM-7000 Patient Monitor is battery or line-powered patient monitor. The patient monitor acquire the physiological signals such as ECG, respiration (RESP), non-invasive blood pressure (NIBP), saturation of pulse oxygen (SpO_2), temperature (TEMP), invasive pressure (IBP), carbon dioxide (CO_2) and anaesthetic gases (AG). These physiological signals are converted into digital data and processed. The monitor examines the data for alarm conditions and presents them on the color TFT display. The monitor also provides advantageous operating control for the user. The optional built-in recorder, the optional CF memory card provides hard copies of all digital data and waveforms as well as tabular and graphic trend information, and storage the previous monitoring data information when power off accidentally.

Statement of intended Use:

The PM-7000 Patient Monitor is intended to be used for monitoring, recording, and alarming of multiple physiological parameters in health care facilities by qualified health care professionals trained in the use of the equipment.

The physiological parameters that can be monitored by the PM-7000 Patient Monitor are: ECG(3-lead or 5-lead or 12-lead selectable), arrhythmia detection, ST Segment analysis, Heart Rate(HR), Respiration Rate(RESP), Non-invasive Blood Pressure (NIBP), Pulse

Oxygen Saturation (SpO_2), Temperature (TEMP), Invasive Blood Pressure(IBP), Pulse Rate(PR), Carbon Dioxide (CO_2), and Anaesthetic Gases(AG).

Its design allows the operator to adjust the settings of parameter alarms that audibly and visually notify the operator when an excursion occurs.

The target populations are human patients ranging from adult to neonate with the exception of the arrhythmia detection and ST Segment analysis, for which the target populations are adult and pediatric only.

The Monitor is not intended for use in a patient's home or residence, or when it has not been ordered by a physician.

Comparison of Technological Characteristics:

Both the PM-7000 Patient Monitor and the predicate PM-9000 Express Patient Monitor (K070791) have the same parameters modules, measurement accessories and modules (software/hardware). That is to say, they have identical parameters subsystems. Both the devices have the main board and host software in common, and identical screen layout (user interface and display style). Parameter measurement performance and function specification of PM-7000 could be proved by the verification and validation of PM-9000 Express (K070791) because both are ensured by same modules and same software.

There are differences only in power supply, key board, and display Screen. The technological differences do not affect the safety or efficacy of the devices. And safety and effectives of PM-7000 could be ensured by the same design control procedure as PM-9000 Express.

Testing:

By risk analysis, verification and validation caused by differences between PM-7000 and PM-9000 Express have been completely conducted according to testing methods that have been cleared in PM-9000 Express (K070791).

Conclusion:

The PM-7000 Patient Monitor is as safe, as effective, and performs as well as the legally marketed predicate device PM Series Patient Monitors, Model PM-9000 Express (K070791).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2007

Shenzhen Mindray Bio-Medical Electronics Co. Ltd.
c/o Ms. Susan D. Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K072346
Trade/Device Name: PM-7000 Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: November 1, 2007
Received: November 2, 2007

Dear Ms. Goldstein-Falk:

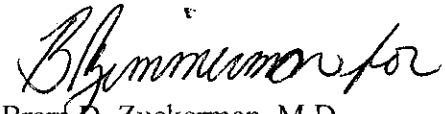
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072346

Device Name: PM-7000 Patient Monitor

Indications for Use:

The PM-7000 Patient Monitor is intended to be used for monitoring, recording, and alarming of multiple physiological parameters in health care facilities by qualified health care professionals trained in the use of the equipment.

The physiological parameters that can be monitored by the PM-7000 Patient Monitor are: ECG(3-lead or 5-lead or 12-lead selectable), arrhythmia detection, ST Segment analysis, Heart Rate(HR), Respiration Rate(RESP), Non-invasive Blood Pressure (NIBP), Pulse Oxygen Saturation (SpO_2), Temperature (TEMP), Invasive Blood Pressure(IBP), Pulse Rate(PR), Carbon Dioxide (CO_2), and Anaesthetic Gases(AG).

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072346